

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

DONNA MENDOZA,
Plaintiff,

v.

INTUITIVE SURGICAL, INC.,
Defendant.

Case No. 18-CV-06414-LHK

ORDER ON MOTIONS IN LIMINE

Re: Dkt. Nos. 94–96, 98

Before the Court are the motions in limine of Plaintiff Donna Mendoza, ECF Nos. 94–96, and the motion in limine of Defendant Intuitive Surgical (“Intuitive”), ECF No. 98. After reviewing the parties’ briefing, the case law, and the record in this case, and balancing the considerations set forth in Federal Rule of Evidence 403, the Court rules as follows:

Mendoza’s Motions in Limine (“MILs”)

Mendoza’s MIL #1: Mendoza moves to exclude evidence of (1) the informed consent documents she signed prior to her surgery; and (2) the conversations she had with Dr. Howard Marcus regarding the risks of surgery. ECF No. 94. Intuitive opposes. ECF No. 106.

Ruling: DENIED WITHOUT PREJUDICE. Specifically, the Court rules as follows.

Mendoza moves to exclude evidence that she gave her informed consent to surgery. Mendoza argues that she has “never alleged a claim for violation of informed consent, and [Intuitive] does not allege that Ms. Mendoza was given inadequate consent by her surgical team.” ECF No. 94 at 2. Mendoza’s claim is instead that “her injuries were caused by the malfunction of a defective product”—a risk of which she was not warned before surgery. *Id.* at 1. Thus, Mendoza argues that admitting evidence of her consent to other surgical risks would be “both irrelevant and unfairly prejudicial.” *Id.* at 2. For support, Mendoza cites *medical malpractice* cases that excluded evidence of informed consent. *Id.* at 2–3.

Intuitive agrees that evidence about informed consent in medical malpractice cases is unfairly prejudicial. ECF No. 106 at 2. Yet Intuitive notes that the instant case is not a medical malpractice case. *Id.* at 3. Intuitive thus makes two arguments against MIL #1. First, Intuitive argues that Mendoza’s cited cases—which all address medical malpractice claims—offer no guidance in the instant case. *Id.* Second, Intuitive argues that MIL #1 is premature. Specifically, “[w]hether the informed consent documents or informed consent conversations are properly admitted as evidence depends on the testimony of Ms. Mendoza and Dr. Marcus about these documents and discussions.” *Id.* In Intuitive’s view, “such testimony might be admissible as affirmative or impeachment evidence against Dr. Marcus or Ms. Mendoza, depending on what either has to say at trial.” *Id.*

The Court agrees with both of Intuitive’s arguments. To start, Mendoza’s cited cases are inapposite. The cited cases excluded evidence of informed consent because, as a matter of law, a patient cannot consent to medical malpractice. *See, e.g.*, ECF No. 94 (quoting and bolding this reasoning from *Wright v. Kaye*, 593 S.E.2d 307, 317 (Va. 2004)). None of the cases weighed the admissibility of informed consent evidence for purposes other than rebutting medical malpractice—let alone for purposes related to the products liability claims at issue here.

Thus, the Court agrees with Intuitive that informed consent evidence might be admissible depending on Mendoza or Dr. Marcus’s testimony. For instance, as Intuitive notes, evidence on informed consent might be admissible as impeachment evidence if a witness were to testify

untruthfully about the scope of informed consent. *See* Fed. R. Evid. 608(b) (discussing scope of impeachment evidence). At this time, however, it is unclear whether Intuitive will even introduce evidence of informed consent—and if so, for what purpose. “[T]o exclude evidence on a motion in limine the evidence must be inadmissible on all potential grounds. Unless evidence meets this high standard, evidentiary rulings should be deferred until trial so that questions of foundation, relevancy, and potential prejudice may be resolved in proper context.” *Yowan Yang v. ActionNet, Inc.*, 2016 WL 8929250, at *2 (C.D. Cal. Feb. 19, 2016) (quotation omitted). Accordingly, the Court DENIES WITHOUT PREJUDICE Mendoza’s MIL #1.

Mendoza’s MIL #2: Mendoza moves to exclude any testimony, statement, or insinuation that the Plaintiff was informed of the nature and risks of a robotically assisted hysterectomy. ECF No. 95. Intuitive opposes. ECF No. 107.

Ruling: DENIED. Specifically, the Court rules as follows.

Mendoza moves to exclude evidence that “bowel injuries—*i.e.* the kind of injury suffered by [Mendoza] in this case—are a ‘known risk’ of the type of surgical procedure [Mendoza] had, regardless of the type of surgical modality used.” ECF No. 95 at 1. Mendoza argues that such “known risk” evidence would be irrelevant and prejudicial. As to relevance, Mendoza argues that known risk evidence would not be probative of what caused Mendoza’s injuries. Specifically, Mendoza asserts that Intuitive will “claim[] (in a conclusory fashion) . . . that something is a ‘known risk[,] [which] is not the same thing as presenting actual evidence of an alternative cause at play.” *Id.* at 2. As for prejudice, Mendoza argues that known risk evidence would “confuse and mislead the jury” and “invite the jury to take a philosophical approach, rather than an evidence-based one.” *Id.* at 3.

The only authority that Mendoza cites for MIL #2 is an excerpt from the deposition of Dr. James Coad, one of Intuitive’s expert witnesses. According to Mendoza, Dr. Coad conceded that Dr. Marcus (Mendoza’s surgeon) did not injure Mendoza’s bowel. *Id.* at 2. Aside from this deposition excerpt, MIL #2 is devoid of any citations to authority—including legal authority.

Intuitive offers four responses to MIL #2. First, Intuitive argues that known risk evidence is relevant because it “tends to prove a non-tortious mechanism of injury.” ECF No. 107 at 2. Specifically, Intuitive experts will attempt to explain that Mendoza’s bowel injury could have “occur[red] in the absence of malpractice of negligence by a surgeon *and* in the absence of any malfunction of Intuitive’s [instruments].” *Id.* Second, Intuitive argues that it will present “actual evidence of an alternative cause” rather than merely “conclusory” assertions. *Id.* This actual evidence will comprise expert testimony that Mendoza’s history of adhesions (bands of scar-like tissue) that could have caused her injury. *Id.* Third, Intuitive argues that Mendoza overstates the import of Dr. Coad’s testimony. Lastly, Intuitive argues that “a review of the law shows that courts find that ‘known complication’ testimony is proper.” *Id.* at 3 (citing cases).

The Court agrees with Intuitive. Known risk evidence would be relevant and not “unfairly prejudic[ial]” under Federal Rule of Evidence 403. As to relevance, Intuitive has explained how—contrary to Mendoza’s unsupported assertion—Intuitive’s experts will present non-conclusory testimony on adhesions, a potential alternative cause of Mendoza’s injury. Causation is a key disputed factual issue in this case. *See* Joint Pretrial Statement at 9, ECF No. 99 (disputing causation). Moreover, Mendoza overstates Dr. Coad’s testimony. Dr. Coad merely testified that Dr. Marcus did not tear, puncture, or crush Mendoza’s bowel. Coad Dep. at 93:14–24. That testimony does *not* necessarily mean that Intuitive caused Mendoza’s injury. Rather, another factor—such as Mendoza’s history of adhesions—might have caused Mendoza’s injury if Intuitive’s proffered expert testimony is credited. Thus, known risk evidence is relevant.

As for prejudice, courts generally hold that the relevance of known risk evidence outweighs any potential prejudice to an injured plaintiff. *See, e.g., Mitchell v. Shikora*, 209 A.3d 307, 319–20 (Pa. 2019) (holding that “the significant consequences of a prohibition on [‘known risk’] evidence tip the scales in favor of admissibility”); *Hillyer v. Midwest Gastrointestinal Assocs., P.C.*, 24 Neb. App. 75, 92–93 (Neb. App. Ct. 2016) (holding that “defendant or nonparty expert witnesses can testify about the risks of the relevant surgical procedures generally”). Mendoza offers no support for deviating from this weight of authority. Indeed, as Intuitive notes,

1 Mendoza fails to cite any authority for her argument against admitting known risk evidence.
2 “[A]rguments that are unsupported by pertinent authority[] are waived.” *E.g., Wells v. Unisource*
3 *Worldwide, Inc.*, 289 F.3d 1001, 1008 (7th Cir. 2002).

4 Excluding known risk testimony would also prejudice Intuitive. Without known risk
5 evidence, the jury might assume that nothing other than the alleged product defect could have
6 caused Mendoza’s injury. That assumption would conclusorily resolve causation, a key disputed
7 factual issue in this case. Joint Pretrial Statement at 9. The jury should have the opportunity to
8 weigh the evidence on causation. Accordingly, the Court DENIES Mendoza’s MIL #2.

9
10 Mendoza’s MIL #3: Mendoza moves to exclude any evidence, testimony, or other reference to the
11 tolling agreement entered into by the parties in this case. ECF No. 96. Intuitive opposes. ECF
12 No. 108.

13 Ruling: GRANTED. Specifically, the Court rules as follows.

14 “[I]n 2014, the parties entered into an agreement to toll the statute of limitations for any
15 potential product liability litigation” concerning Mendoza’s injuries. ECF No. 96. Mendoza moves
16 to exclude any reference to this tolling agreement on three grounds: (1) irrelevance;
17 (2) unfair prejudice; and (3) Federal Rule of Evidence 408’s limitations on admitting evidence of
18 compromise negotiations. *Id.* at 1–2.

19 Intuitive responds that the tolling agreement is relevant to Intuitive’s affirmative defense of
20 laches. ECF No. 108 at 2 (citing Joint Pretrial Statement at 4). Specifically, Intuitive argues that
21 “the tolling agreement could be relevant to help provide the jury with a timeline about when
22 Plaintiff first contemplated filing a claim against Intuitive and whether her claim is timely.” *Id.*
23 Intuitive also argues that Mendoza would not be unfairly prejudiced, and that Rule 408 does not
24 exclude the tolling agreement.

25 The Court agrees with Mendoza that the tolling agreement is irrelevant, and so need not
26 reach Mendoza’s arguments on prejudice and Rule 408. The tolling agreement is irrelevant
27 because it would be introduced to support laches—an *equitable* defense that is unavailable to

Intuitive in this action at law. Two binding precedents require this conclusion. First, in *Soliman v. Philip Morris Inc.*, the Ninth Circuit held that “the doctrine of laches does not apply” in a products liability action for damages. 311 F.3d 966, 975 n.13 (9th Cir. 2002). The Ninth Circuit reasoned that because the *Soliman* plaintiff sought monetary relief—which is “legal, not equitable”—the relevant statute of limitations applied instead. *Id.* at 971, 975 n.13. Here too, Mendoza seeks purely monetary relief for product liability claims. *See* Joint Pretrial Statement at 7 (stating relief sought).

Moreover, as in *Soliman*, a statute of limitations governs the timeliness of the products liability claims here. Specifically, the parties’ tolling agreement “toll[ed] the statute of limitations for any potential product liability litigation.” ECF No. 96. The parties have since stipulated to Indiana law for Mendoza’s product liability claims, which assert negligence and strict liability. *See* Joint Pretrial Statement at 2, 11 (stipulating and listing claims); Indiana Code § 34-20-2-2 (discussing “reasonable care” standard for design defect and failure to warn). Indiana law provides a statute of limitations for “any product liability action in which the theory of liability is negligence or strict liability.” *Florian v. Gatx Rail Corp.*, 930 N.E.2d 1190, 1200 (Ind. Ct. App. 2010) (discussing Indiana Code § 34-20-3-1).

Second, the United States Supreme Court has confirmed that laches is not a defense to claims governed by a statute of limitations. In *Petrella v. Metro-Goldwyn-Mayer, Inc.*, the Supreme Court explained that “laches is a defense developed by courts of equity; its principal application was, and remains, to claims of an equitable cast for which the Legislature has provided no fixed time limitation.” 572 U.S. 663, 678 (2014). Here, a statute of limitations governs Mendoza’s claims, as recognized by the parties’ tolling agreement. Thus, Intuitive cannot raise laches as a defense.

Finally, as discussed above, Intuitive’s only proffered reason for introducing the tolling agreement would be to support a defense of laches. ECF No. 108 at 2. Accordingly, the tolling agreement is irrelevant, and Mendoza’s MIL #3 is GRANTED.

Intuitive’s Motion in Limine (“Motion”)

Intuitive’s MIL: Intuitive moves to exclude any evidence or argument concerning *the content of* other legal claims, complaints, or incidents (referred to generally as “complaints”) other than any complaint about the surgery at issue in this litigation. ECF No. 98 at 2 (emphasis in original). Mendoza opposes. ECF No. 103.

Ruling: GRANTED as to the content of Medical Device Reporting (“MDR”) or MedWatch reports, but DENIED WITHOUT PREJUDICE as to other complaints. Specifically, the Court rules as follows.

Intuitive moves to exclude a broad swath of evidence: “any evidence or argument concerning *the content of* any claims, complaints, or incidents (referred to generally as ‘complaints’) other than any complaint about the surgery at issue in this litigation.” ECF No. 98 at 2 (emphasis in original). Yet the focus of Intuitive’s motion—and the only evidence Mendoza plans to introduce—are certain formal “reports filed with the FDA[] called ‘MedWatch reports’ or ‘MDRs.’” *Id.*; accord ECF No. 103 at 2 n.1 (representing that Mendoza “concentrates her response on formal complaints submitted by physicians, hospitals[,] or Intuitive to the FDA – not other lawsuits”); Joint Pretrial Statement at 16 (disputing whether MDR reports are admissible). Specifically, Mendoza represents that she “will only offer evidence of other lawsuits” in addition to MDRs “if Intuitive misleads the jury in any way that could be rebutted by the evidence of many lawsuits against the company.” ECF No. 103 at 2 n.1. Thus, it would be premature for the Court to rule on proffered evidence other than MDRs. *See, e.g., Yang*, 2016 WL 8929250, at *2 (deferring ruling on evidence until trial).

As for MDRs, Intuitive argues they are inadmissible on three independent grounds: (1) inadmissible hearsay; (2) a statutory bar under 21 U.S.C. § 360i(b)(3); and (3) unfair prejudice and waste of time under Federal Rule of Evidence 403. *Id.* at 2–4. The Court need only reach the statutory bar because it is dispositive. 21 U.S.C. § 360i(b)(3) provides that MDRs “shall not be admissible into evidence or otherwise used in any civil action involving private parties” if two conditions are met. First, the MDR at issue must be made by one of three types of entities:

(A) a device user facility [which “means a hospital, ambulatory surgical facility, nursing home, or outpatient treatment facility which is not a physician’s office,” *id.* § 360i(b)(6)(A)],

(B) an individual who is employed by or otherwise formally affiliated with such a facility, or

(C) a physician who is not required to make such a report.

Id. § 360i(b)(3). Second, the MDR must not contain false information that the reporting entity knew was false. *Id.* Pursuant to this statutory bar, many courts have excluded the content of MDRs as inadmissible or undiscoverable. *See, e.g., In re Medtronic, Inc.*, 184 F.3d 807, 811 (8th Cir. 1999) (citing 21 U.S.C. § 360i(b)(3) to issue writ of mandamus against discovery of MDR content); *Herrera-Nevarez by Springer v. Ethicon, Inc.*, No. 12-CV-2404-MFK, 2017 WL 3381718, at *5 (N.D. Ill. Aug. 6, 2017) (excluding MDRs pursuant to 21 U.S.C. § 360i(b)(3)).

On the briefing here, the proffered MDRs here cannot circumvent 21 U.S.C. § 360i(b)(3)’s command that MDRs “shall not be admissible into evidence or otherwise used in any civil action involving private parties.” Indeed, Mendoza fails to even mention—let alone analyze—21 U.S.C. § 360i in her response to Intuitive’s motion. Mendoza has thus forfeited any opposition to 21 U.S.C. § 360i(b)(3) excluding the content of MDRs in this case. *See, e.g., Maciel v. Cate*, 731 F.3d 928, 932 n.4 (9th Cir. 2013) (holding that “failing to address [an argument] in [] reply brief” forfeits the argument); *Stichting Pensioenfonds ABP v. Countrywide Fin. Corp.*, 802 F. Supp. 2d 1125, 1132 (C.D. Cal. 2011) (collecting cases holding same).

Rather than analyze 21 U.S.C. § 360i, Mendoza cites two cases for the unrelated proposition that MDRs are not hearsay. Neither case shows that Mendoza’s proffered MDRs can circumvent 21 U.S.C. § 360i(b)(3). In the first case, an Arkansas district court quoted 21 U.S.C. § 360i(b)(3) and conclusorily held that MDRs are admissible based on an unexplained “substantially similar test,” which is nowhere in the statute. *Chism v. Ethicon Endo-Surgery, Inc.*, No. 4:08-CV-00341-WRW, 2009 WL 3066679, at *1 (E.D. Ark. Sept. 23, 2009). Furthermore, the *Chism* court briefly quoted the statute’s legislative history in a footnote, but the substantially similar test is equally absent there. *Id.* at n.9. Thus, the Court is not persuaded by *Chism*. Moreover, Mendoza herself does not even argue that her proffered MDRs satisfy “the substantially

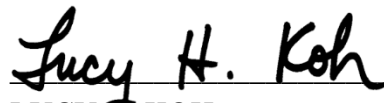
1 similar test.” In fact, she does not mention 21 U.S.C. § 360i at all. Thus, *Chism* fails to support
2 Mendoza.

3 In the other case cited by Mendoza, a West Virginia district court relied on *Chism* to hold
4 that “MDRs that do not fall within the scope of § 360i” are admissible. *In re C.R. Bard, Inc.,*
5 *Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:10-CV-01224, 2013 WL 3282926, at *5 (S.D.W. Va.
6 June 27, 2013), *on reconsideration*, 2013 WL 11089794 (S.D.W. Va. July 1, 2013), *and aff’d in*
7 *part, rev’d in part*, 810 F.3d 913 (4th Cir. 2016). Yet as discussed above, *Chism* is unpersuasive.
8 Moreover, Mendoza fails to argue that her proffered MDRs would “not fall within the scope of
9 § 360i.” *Id.* Thus, *In re C.R. Bard* also fails to support the admissibility of MDRs here.

10 In sum, the Court GRANTS Intuitive’s motion as to the content of MDRs (or “MedWatch”
11 reports). As for other complaints—such as evidence of other lawsuits—the Court DENIES
12 WITHOUT PREJUDICE Intuitive’s motion as premature.

13 **IT IS SO ORDERED.**

14 Dated: May 11, 2021

15 
16 LUCY H. KOH
17 United States District Judge